



October 25, 2022

VIA Email & U.S. MAIL

Jennifer Knopp, RN
Director of Surgical Services
Chesapeake Eye Surgery Center
2002 Medical Parkway, Suite 330
Annapolis, Maryland 21401

**Re: Chesapeake Eye Surgery Center, LLC
Certificate of Need Application
Docket No. 22-03-2461
Completeness Questions**

Dear Ms. Knopp:

Maryland Health Care Commission (Commission) staff has reviewed the Certificate of Need (CON) application from the Chesapeake Eye Surgery Center, LLC (CESC) to add one operating room (OR) to establish an Ambulatory Surgical Facility (ASF). It was determined by staff that the application submitted by CESC is outdated and does not reflect the current State Health Plan (SHP) Chapter that became effective in October 2021. The statutory revision eliminated the requirement to obtain a CON for a facility with two ORs or less, and under the current regulatory language, CESC is an Ambulatory Surgery Center (ASC-2). As an ASC-2, when adding a third OR, CESC would be establishing a new ASF, not expanding an existing facility. As a result of these issues, there are several areas in the application which were found to be incomplete and therefore staff requests that you provide responses to the following questions:

Project Budget

1. In the body of the application, the estimated project cost is \$530,137; in Table E: Project Budget, the estimated total project cost is \$636,164. Please explain the discrepancy.

Information Regarding Charges

2. List any complaints made the Consumer Protection Division of the Attorney General of Maryland or to the Maryland Insurance Administration about CESC. Provide detailed information on any determinations and actions taken to correct any deficiencies.
3. Provide the names of the health carrier networks in which CESC currently participates and affirm that it will provide this information to the public, upon inquiry or as required by applicable regulations.
4. Provide the names of the health carrier networks in which each surgeon and other health care practitioner that provides services at the facility currently participates and affirm that it will provide this information to the public, upon inquiry.

Information Regarding Procedure Volume

5. Provide volume information for CESC's 10 most frequently performed procedures by surgical specialty for the last 12 months. Affirm that this list will be updated annually.

Charity Care

6. Provide a written policy for the provision of charity care that includes financial assistance regarding free and reduced-cost care to uninsured, underinsured, or indigent patients and the policy shall provide ambulatory surgical services on a charitable basis to qualified persons consistent with the policy.
7. Identify the specific language from your policy regarding a determination of probable eligibility within two business days of request for charity or reduced fee care or application for Medicaid.
8. Quote the specific language from the policy that describes the determination of probable eligibility and give a citation to the location within the policy.
9. Provide a copy of your procedures, if any, and other documents that detail your process for making a determination of probable eligibility and your procedures for making a final determination.



10. Provide copies of any application and/or other forms involved in the process for making a determination of probable eligibility within two business days.

***NOTE:** Requiring a completed application with documentation for determination of probable eligibility for charity care does not comply with this standard, which is intended to ensure that a procedure is in place to inform a potential charity care/reduced fee recipient of his/her probable eligibility within two business days of initial inquiry or application for Medicaid based on a simple and expeditious process.*

A two-step process that allows for 1) a probable determination to be communicated within two days based on an abridged set of information, followed by 2) a final determination based on a completed application with the required documentation is permissible. The policy must include the more easily navigated determination of probable eligibility. See COMAR 10.24.11.05A(3).

11. Identify the specific language from the policy that describes the method of implementing and provide a copy of the notice posted in the registration area and business office. Please describe the annual notice and provide a copy of it or description of it if a copy cannot be provided.
12. Identify the specific language from the policy that describes the provisions for the sliding fee scale and time payment plans and provide a citation to the location within the policy where the language can be found. Your criteria shall include, at a minimum, the eligibility criteria listed in this Standard.
13. Affirm that the facility will provide charitable surgical services to indigent patients that are equivalent to at least the average amount of charity care provided by ambulatory surgical facilities in the most recent year reported, measured as a percentage of total operating expenses.
14. Provide the most recent five years of CESC's historical data regarding the provision of charity care.
15. Describe the plan to meet the charity care commitment. A response for demonstrating a serious "specific plan for achieving the level of charitable care provision to which it is committed" should:



- (i) Identify the specific social service organizations/agencies that an applicant has contacted or plans to contact to inform them of the availability of charity care, and;
 - (ii) Incorporate a real-time reporting mechanism that will alert management regarding its progress toward its charity care commitment, and a statement of what actions will then be taken.
16. Describe how CESC is related to the Operation Sight Program.
- (i) When and how did CESC become affiliated with Operation Sight?
 - (ii) Does CESC process the applications, if not, how is this tracked?
 - (iii) How many CESC providers are registered to participate?
 - (iv) How is this program communicated to patients?
 - (v) How many CESC patients are served annually?
 - (vi) Does CESC provide charitable care for any procedures outside the Operation Sight program?

Quality of Care

17. Provide a copy of documentation from CMS that show that CESC is in compliance with the conditions of participation of the Medicare and Medicaid programs
18. Demonstrate that CESC is enrolled in the AMBULATORY SURGERY CENTER QUALITY REPORTING program, and that it has submitted its data. Here are the related website: <https://www.qualityreportingcenter.com/asc/resources/>, <https://www.qualityreportingcenter.com/asc/>
19. As CESC is seeking to establish a new ASF, it must demonstrate that the proposed facility will meet or exceed the minimum requirements for licensure in Maryland in the areas of administration, personnel, surgical services provision, anesthesia services provision, emergency services, hospitalization, pharmaceutical services, laboratory and radiologic services, medical records, and physical environment, as described in COMAR 10.24.11.05A(4)(d). In order to fulfill this requirement, the applicant should:
- (i) Provide a description of the requirements for licensure and the steps you will take to meet these requirements in Maryland to demonstrate your understanding of the process.



- (ii) Affirm that, within two years of initiating service at the facility, it will obtain accreditation by the Joint Commission, the Accreditation Association for Ambulatory Health Care, or the American Association for Accreditation of Ambulatory Surgery Facilities or another accreditation organization recognized by the Centers for Medicare and Medicaid Services as acceptable for obtaining Medicare certification and approved by the State of Maryland; and
 - (iii) Acknowledge in writing that if the facility fails to obtain the accreditation in subparagraph (ii) (above) on a timely basis, it shall voluntarily suspend operation of the facility.
20. If the applicant or a related entity that currently or previously has operated or owned one or more ASCs or ambulatory surgical facilities in or outside of Maryland in the five years prior to the applicant's filing of an application to establish an ambulatory surgical facility, then provide details regarding the quality of care provided at each such ASC or ambulatory surgical facility including information on licensure, accreditation, performance metrics, and other relevant information.

Need - Minimum Utilization for Establishment of a New or Replacement Facility

Under the current State Health Plan Chapter, CESC is seeking to establish a new ASF, therefore, a response to COMAR 10.24.11.05B(2) is required. Please see the Review Guide for information on how to satisfy this standard.

21. Provide a needs assessment demonstrating that each proposed operating room is likely to be utilized at optimal capacity or higher levels within three years of the initiation of surgical services at the proposed facility, consistent with Regulation .06 of the Chapter by providing the expected utilization level for each operating room for the first three years of initiating surgical services at the facility. Explain the assumptions used and reasons for changes in projected volume, if applicable.
22. Submit a needs assessment that includes the following:
- (i) Historic trends in the use of surgical facilities for outpatient surgical procedures by the proposed facility's likely service area population by providing annual number of cases across multiple years and cite the data source;
 - (ii) The operating room time required for surgical cases projected at the proposed facility by surgical specialty or, if approved by Commission staff, another set of categories by providing estimated time per case and cite the data source, and



- (iii) Documentation of the current surgical caseload of each physician likely to perform surgery at the proposed facility by providing each physician's current caseload, expected caseload at the proposed facility, and the referral source where these cases will transfer from. Would need to produce signed statements of intent to bring cases there and provide documented projections of volume.

Financial Feasibility

- 23. Document that utilization projections are consistent with observed historic trends in use of each applicable service by the likely service area population of the facility.
- 24. Document that staffing and overall expense projections are consistent with utilization projections and are based on current expenditure levels and reasonably anticipated future staffing levels as experienced by the applicant facility, or, if a new facility, the recent experience of similar facilities.
- 25. Document that CESC will generate excess revenues over total expenses for the specific services affected by the project (including debt service expenses and plant and equipment depreciation), if utilization forecasts are achieved for the specific services affected by the project within five years of initiating operations.

Impact

- 26. CESC is seeking to establish a new ASF and is required to present an impact assessment, in addition to addressing COMAR 10.24.01.08G(3)(f):
 - (i) The number of surgical cases projected for the facility and for each physician and practitioner;
 - (ii) A minimum of two years of historic surgical case volume data for each physician or other practitioner, identifying each facility at which cases were performed and the average operating room time per case. Calendar year or fiscal year data may be provided if the time period is identified and is consistent for all physicians and other practitioners; and
 - (iii) The proportion of case volume expected to shift from each existing facility to the proposed facility.
- 27. Given that it is common for surgeons to be credentialed with more than one surgical facility or hospital, provide an assessment of the impact of the proposed project on surgical case volume at hospitals:



- (i) If the applicant's needs assessment includes surgical cases performed by one or more physicians who currently perform cases at a hospital within the defined service area of the proposed ambulatory surgical facility that, in the aggregate, account for 18 percent or more of the operating room time in use at that hospital, the applicant shall include, as part of its impact assessment, a projection of the levels of use at the affected hospital for at least three years following the anticipated opening of the proposed ambulatory surgical facility.
- (ii) The operating room capacity assumptions in Regulation .06A of this Chapter and the operating room inventory rules in Regulation .06C of this Chapter shall be used in the impact assessment

Need COMAR 10.24.01.08G(3)(b).

28. Provide a more detailed explanation of the need for modernization, including the impact to the service area population.

Tables 1 and 2

29. Explain why there are no procedures in ORs and no cases in procedure rooms reflected in the statistical projections for the entire facility (Table 1) and proposed project (Table 2).

30. Provide the average turnover time for procedures performed in the ORs.

Availability of More Cost-Effective Alternatives

31. Provide information on the level of effectiveness or problem resolution that each alternative that was examined would be likely to achieve and the costs of each alternative.

The cost analysis should go beyond development cost to consider life cycle costs of project alternatives. This narrative should clearly convey the analytical findings and reasoning that supported the project choices made. It should demonstrate why the proposed project provides the most effective goal and objective achievement or the most effective solution to the identified problem(s) for the level of cost required to implement the project, when compared to the effectiveness and cost of alternatives and include the alternative of providing the service through alternative existing facilities.

Viability of the Proposal



32. Provide audited financial statements for the past two years for all applicant entities and parent companies to demonstrate the financial condition of the entities involved and the availability of the equity contribution.

If audited financial statements are not available for the entity or individuals that will provide the equity contribution, submit documentation of the financial condition of the entities and/or individuals providing the funds and the availability of such funds. Acceptable documentation is a letter signed by an independent Certified Public Accountant. Such letter shall detail the financial information considered by the CPA in reaching the conclusion that adequate funds are available.

33. Describe and document relevant community support for the proposed project.
34. Explain the process for completing the project design, obtaining State and local land use, environmental, and design approvals, contracting and obligating the funds within the prescribed time frame. Describe the construction process or refer to a description elsewhere in the application that demonstrates that the project can be completed within the applicable time frame(s).

Tables 3 and 4

35. Identify whether the information in Tables 3 and 4 are calendar year or fiscal year?
36. Identify if the percentages in Section 4B of Tables 3 and 4 are patient days, visits, or procedures?
37. Under the “Patient Mix” sections of these tables, Self-Pay accounts for between 36 and 40 percent of the total revenue but between one and a half and four percent of your patient days/visits/procedures. Explain the difference or discrepancy between the percentage of total revenue and percentage of patient days/visits/procedures.

Provide a detailed description of what is included in the “contractual services” on Table 4.

38. Provide more detail on the “Other Expenses” on lines 2.j., 4.a.6., and 4.b.6. on Table 4 are.

Impact on Existing Providers and the Health Care Delivery System



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October 25, 2022

Page 9

39. Identify all sources of information and assumptions used in CESC's impact analysis with respect to demand for services, payer mix, access to service and cost to the health care delivery system including relevant populations considered, and changes in market share, with information that supports the validity of these assumptions.
40. Provide a payor mix analysis of all other existing health care providers that are likely to experience some impact on payer mix as a result of CESC's project.
41. Provide an analysis on this project's costs to the health care delivery system.
42. Provide a summary description of the impact of the proposed project on the applicant's costs and charges, consistent with the information provided in the Project Budget, the projections of revenues and expenses, and the work force information.

Please submit four copies of the responses to above questions and requests for additional information within ten working days of receipt. Also submit the response electronically, in both Word and PDF format, to Ruby Potter (ruby.potter@maryland.gov). If additional time is needed to prepare a response, please let me know at your earliest convenience.

As with the request itself, all information supplementing the request must be signed by person(s) available for cross-examination on the facts set forth in the supplementary information, who shall sign a statement as follows: "I hereby declare and affirm under the penalties of perjury that the facts stated in this application and its attachments are true and correct to the best of my knowledge, information, and belief."

Should you have any questions regarding this matter, please contact me by phone at (804) 347-6024 or by email at laura.hare1@maryland.gov.

Sincerely,



Laura Hare Nirschl
CON Program Manager

cc: Paul Parker, Director, Center for Health Care Facilities Planning & Development
Wynee Hawk, Chief, Certificate of Need
Nilesh Kalyanaraman, M.D., Health Officer, Anne Arundel County

